

State Intellectual Property Office of P.R.C

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| Addressee: Ms. Yeping DING, Mr. Tianshu ZHANG Tee & Howe Intellectual Property Attorneys Suite 718 Capital Times Square, 88 Xichang'an Street, Xicheng District, Beijing 100031 | Issuing Date: May 8, 2009 |
| Filing Number: 2005800094953 | |

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| Applicant: Astellas Pharma Inc. |
| Invention Title: Composition of Solifenacin or Salt thereof for Use in Solid Formulation |

Notification of the Third Office Action

1. ☒ The further examination is conducted on the basis of the Response submitted on December 31, 2008 by the applicant to the 3rd Office Action.
☐ The further examination is conducted on the basis of the reexamination decision made on ____ by the Patent Reexamination Board.
2. ☐ The amendments to the application documents submitted on _____, do not meet the requirement of Paragraph 3 of Rule 51 of the Implementing Regulations of the Chinese Patent Law.
3. The further examination is conducted on the basis of the following application documents:
☐ Amended documents enclosed with the response.
☒ Application documents covered in the preceding Office Action and amended documents enclosed with the response.
☐ Application documents covered in the preceding Office Action.
☐ Application documents determined in the reexamination decision.
4. ☒ No new reference is cited in the notification.
☐ The following references are cited in the notification (the reference No. will be used in the further procedure of examination):

| No. | References or Titles | Publication Date (or Filing Date of the Conflict Application) |
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5. Conclusive opinion:
☐ regarding the Description
☐ the content of the application belongs to the scope of Article 5 of the Chinese Patent Law which cannot be granted.
☐ the description is not in conformity with the provisions of Paragraph 3 of Article 26 of the Chinese Patent Law.
☐ the amendment of the Description is not in conformity with the provisions of Article 33 of the Chinese Patent Law.
☐ the presentation manner of the description is not in conformity with Rule 18 of the Implementing

Regulations of the Chinese Patent Law.

☒ regarding the Claims

☐ Claims ____ do not possess the novelty under Paragraph 2 of Article 22 of the Chinese Patent Law.

☐ Claims ____ do not possess the inventiveness under Paragraph 3 of Article 22 of the Chinese Patent Law.

☐ Claims ____ do not possess the practical applicability under Paragraph 4 of Article 22 of the Chinese Patent Law.

☐ Claims ____ fall in the scope of Article 25 of the Chinese Patent Law which can not be granted.

☒ Claims **10 and 11** do not meet the requirement of Paragraph 4 of Article 26 of the Chinese Patent Law.

☐ Claims ____ do not meet the requirement of Paragraph 1 of Article 31 of the Chinese Patent Law.

☐ Claim ____ does not meet the requirement of Article 33 of the Chinese Patent Law.

☐ Claims ____ do not comply with the interpretation of invention under Paragraph 1 of Rule 2 of the Implementing Regulations of the Chinese Patent Law.

☐ Claims ____ do not meet the requirement of Paragraph 1 of Rule 13 of the Implementing Regulations of the Chinese Patent Law.

☐ Claim ____ does not meet the requirements of Rule 20 of the Implementing Regulations of the Chinese Patent Law.

☐ Claims ____ do not meet the requirements of Rule 21 of the Implementing Regulations of the Chinese Patent Law.

☐ Claims ____ do not meet the requirements of Rule 22 of the Implementing Regulations of the Chinese Patent Law.

☐ Claims ____ do not meet the requirements of Rule 23 of the Implementing Regulations of the Chinese Patent Law.

☒ **Claims 1-9 do not meet the requirements of Paragraph 3 of Rule 51 of the Implementing Regulations of the Chinese Patent Law**

☐ Divisional application do not meet the requirements of Paragraph 1 of Rule 43 of the Implementing Regulations of the Chinese Patent Law.

Please refer to the text of the notification in detail for the above.

6. Based on the above conclusive opinion, the examiner points out that

☐ applicant should amend the application documents according to the requirements of the text of the notification.

☒ applicant should state the reason that the application may be granted a patent right in the observation and amend the application documents according to the teaching of the text of the notification, otherwise, the application may not be granted.

☐ no any substantive contents to be granted are presented in the application. If the applicant does not submit his observation or his observation is not reasonable, the application will be rejected.

7. **Following items shall come to applicant's attention:**

(1) According to Article 37 of the Chinese Patent Law, applicant should submit his observation within 2 months from the date he receives the notification. If, without any justified reason, the time limit for making a response is not met, the application will be deemed to be withdrawn.

(2) The amendments to the application documents should meet the requirements of Article 33 of the Chinese Patent Law and of Rule 51 thereof. The amendment text should be submitted in two

copies and the amending manner should comply with the relevant regulations of the Examination Guide.

(3) The observation and / or amendment documents should be mailed to or submitted directly to the Receiving Section of the China Patent Office, otherwise, the submitted documents have no legal effect.

(4) The applicant and / or attorney may not meet the examiner if an appointment has not been made.

8. The text of this notification consists of 2 pages, including the following annexes:

☐ page(s) of copy of the cited reference.

☐

Text of the Third Office Action

Application No.: 2005800094953

The Examiner has examined the Observation and the amended claims submitted on December 31, 2008. The Examiner's comments upon further examination of the present application are as follows:

In accordance with the Paragraph 3 of the Rule 51 of the Implementing Regulations of the Chinese Patent Law, where the applicant amends the application after receiving the notification of opinions of the examination as to substance of the Patent Administration Department under the State Council, he shall make the amendment as required by the notification. However, the newly amended claim 1 is directed to a process for producing a composition of solifenacin or a salt thereof for use in a solid formulation. The technical solution of the amended claim 1 is not mentioned in the originally filed Claims. So, the amended claim 1 is a newly added independent claim, which belongs to the 4th situation not being acceptable under the Paragraph 3 of the Rule 51 of the Implementing Regulations of the Chinese Patent Law according to the provisions of Guideline for Examination, Part II, Chapter 8, 5.2.1. Furthermore, the amended dependent claims 2-9 further define claim 1, thus, claims 2-9 are not accepted yet. Therefore, claims 1-9 do not meet the requirements of Paragraph 3 of Rule 51 of the Implementing Regulations of the Chinese Patent Law. The applicant should, within the term specified in this Office Action, delete the amendments being not compliance with the Second Office Action, otherwise, said amendments can not be accepted. If a response can not be submitted before the deadline, the present application is deemed to be withdrawn. If a response is submitted in due time, but no amendment is filed, or the amendments not being compliance with the Second Office Action is not deleted, or other issues being not compliance with the Paragraph 3 of the Rule 51 of the Implementing Regulations of the Chinese Patent Law exist, the Examiner will grant a patent to the previous application to which the above amendments not being compliance with the Second Office Action is not made, or reject the previous application.

Claims 10 and 11 are directed to a pharmaceutical composition of solifenacin or a salt thereof for use in a solid formulation, respectively, wherein the inhibitor of amorphous preparation generalizes a relatively wide range, however, the Description only discloses a technical solution that said inhibitor of amorphous preparation is polyoxyethylene. A person skilled in the art knows that the physical and chemical properties of different compounds having the same structures may be different greatly. Thus, according to the disclosure of the Description, it is hard to predict that all the technical solutions of claims 10 and 11 can solve the technical problems of the present application and achieve the same technical effects. So, claims 10 and 11 is rejected under Paragraph 4 of Rule 26 of the Chinese Patent Law for not supporting by the Description.

Based on above reasons, the current application cannot be granted as it is. The applicant should, within the term specified in this office action, observe the reasons that the application shall be granted and/or amend the claims with respect to the above-mentioned issues. Otherwise, the application will be rejected in accordance with the law. Please note that any amendment to application shall not go beyond the scope as defined by the initially filed description and claims. When filing an amendment to the application, the applicant should submit: 1) a marked-up copy of amendment to the specification showing any of insertions, deletions, or substitutions by using permanent ink; and 2) a clean copy of the amendment to replace the corresponding originals. Those two copies should be consistent with each other regarding the content.

Examiner: Dan MAO
Code: 8227



中华人民共和国国家知识产权局

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| 100031 北京市西长安街 88 号首都时代广场 718 北京天昊联合知识产权代理有限公司 丁业平,张天舒 | 发文日 |
| 申请号: 2005800094953 | |
| 申请人: 安斯泰来制药株式会社 | |
| 发明名称: 用于固体制剂的索非那新或其盐的组合物 | |

第 3 次审查意见通知书

1. ☒ 审查员已收到申请人于 2008 年 12 月 31 日提交的意见陈述书,在此基础上审查员对上述专利申请继续进行实质审查。

☐ 根据国家知识产权局专利复审委员会于 年 月 日作出的复审决定,审查员对上述专利申请继续实质审查。

☐

2. ☐ 申请人于 年 月 日提交的修改文件,不符合专利法实施细则第 51 条第 3 款的规定。

3. 继续审查是针对下述申请文件进行的:

☐ 上述意见陈述书中所附的经修改的申请文件。

☒ 前次审查意见通知书所针对的申请文件以及上述意见陈述书中所附的经修改的申请文件替换页。

☐ 前次审查意见通知书所针对的申请文件。

☐ 上述复审决定所确定的申请文件。

☐

4. ☒ 本通知书未引用新的对比文件。

☐ 本通知书引用下述对比文件(其编号续前,并在今后的审查过程中继续沿用):

编号

文件号或名称

公开日期(或抵触申请的申请日)

5. 审查的结论性意见:

☐ 关于说明书:

☐ 申请的内容属于专利法第 5 条规定的不授予专利权的范围。

☐ 说明书不符合专利法第 26 条第 3 款的规定。

☐ 说明书的修改不符合专利法第 33 条的规定。

☐ 说明书的撰写不符合专利法实施细则第 18 条的规定。

☐

☒ 关于权利要求书:

☐ 权利要求 不具备专利法第 22 条第 2 款规定的新颖性。

☐ 权利要求 不具备专利法第 22 条第 3 款规定的创造性。

☐ 权利要求 不具备专利法第 22 条第 4 款规定的实用性。

☐ 权利要求 属于专利法第 25 条规定的不授予专利权的范围。

☒ 权利要求 10, 11 不符合专利法第 26 条第 4 款的规定。

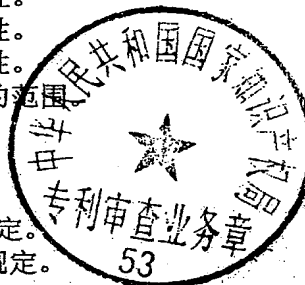
☐ 权利要求 不符合专利法第 31 条第 1 款的规定。

☐ 权利要求 的修改不符合专利法第 33 条的规定。

☐ 权利要求 不符合专利法实施细则第 2 条第 1 款的规定。

☐ 权利要求 不符合专利法实施细则第 13 条第 1 款的规定。

☐ 权利要求 不符合专利法实施细则第 20 条的规定。



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回函请寄: 100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收
(注: 凡寄给审查员个人的信函不具有法律效力)

第三次审查意见通知书正文

申请号：2005800094953

申请人于2008年12月31日提交了意见陈述书和经过修改的申请文件，审查员在阅读了上述文件后，对本申请继续进行审查，提出如下审查意见。

专利法实施细则第51条第3款规定，申请人在收到国务院专利行政部门发出的审查意见通知书后对专利申请文件进行修改的，应当按照通知书的要求进行修改。新修改的权利要求1要求保护一种制备用于固体制剂的索非那新或其盐的组合物的方法，该独立权利要求限定的技术方案在原权利要求书中未出现过，是增加的新的独立权利要求，属于审查指南第二部分第八章5.2.1中规定的不符合专利法实施细则第51条第3款的修改的第（4）种情形而不予接受，由于新修改的从属权利要求2-9是对权利要求1的进一步限定而同样不予接受。因此，权利要求1-9不符合专利法实施细则第51条第3款的规定。申请人应当在指定答复期限内删除不符合前次通知书要求的修改内容，否则该修改文本不能被接受。如果逾期不答复，则该申请将被视为撤回；如果虽然按期答复但未提交修改文本或重新提交的修改文本中未删除不符合前次通知书要求的修改内容，或者出现其他不符合专利法实施细则第51条第3款的内容，则将对修改前的文本作出授权或驳回决定。

权利要求10，11分别要求保护一种用于固体制剂的索非那新或其盐的药物组合物。其中，所述的无定形抑制剂概括了宽泛的范围，而说明书仅公开了所述的无定形抑制剂为聚乙二醇的相应技术方案，本领域技术人员可知，具有共同结构的化合物的理化性质也可能存在很大差异，根据说明书公开的内容无法预期权利要求所要保护的技术方案均能解决本发明所要解决的技术问题，达到相同的技术效果。因此，权利要求10，11没有以说明书为依据，得不到说明书的支持，不符合专利法第26条第4款的规定。

申请人应当在本通知书指定答复期限内，针对上述审查意见进行答复，并克服申请中存在的上述缺陷，否则本申请难以获得批准。对申请文件的修改应当符合专利法第33条的规定，不得超出原说明书和权利要求记载的范围。申请人提交的修改文件应当包括：修改涉及部分的原文复印件，采用红色钢笔或红色圆珠笔在该复印件上标注出所作的增加、删除或替换；重新打印的替换页（一式两份），用于替换相应的原文。申请人应当确保上述两部分在内容上的一致性。

审查员：毛丹

代码：8227